

II. REMARKS

Before the amendments made herein, claims 1, 5 - 13 and 16 - 35 were pending. Claim 36 has been added herein. Accordingly, after entry of the amendments made herein, claims 1, 5 - 13 and 16 - 36 will be pending.

A. Regarding the amendments.

Claim 1 has been amended herein to recite that the claimed therapeutic agent includes the disaccharide of formula I. The amendment is supported in the specification, for example, at page 9, lines 18-19, which discloses that oligosaccharides of up to 10 units can contain this disaccharide.

Claim 18 has been amended to claim 1. In addition, new claim 36 is similar to claim 1, except that it does not recite lung cancer. The new claim is supported in the specification, for example, at page 18, line 19 to page 19, line 4.

Because the amendments made herein are fully supported by the specification, no issue of new matter arises.

B. Regarding priority

The Action alleges that priority (with respect to claims 11 and 27) is denied because the priority applications allegedly do not support the mechanism of action of the specifically claimed heparin or heparin sulfate derivatives.

In response, Applicants respectfully point out that, even if true, it is irrelevant. Claims 11 and 27 do not recite the mechanism of action. Rather, these claims merely recite the derivatives. Accordingly, priority of these claims is respectfully requested.

C. Regarding the indefiniteness rejection

Claims 1, 8, 10, 16 to 19, 21, 25 and 30 to 35 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Specifically, the Action alleges that the phrase “sulfated glucosamine derivative of heparin or heparin-sulfate” is indefinite because it is not clear what compounds would be considered as sulfated derivatives of heparin or heparin-sulfate. Applicants respectfully traverse the rejection.

Claims 1 and 18 (and all claims dependent thereon) have been amended by deleting the phrase “sulfated glucosamine derivative of heparin or heparin-sulfate.” Accordingly, Applicants respectfully request that this rejection be withdrawn.

D. Regarding the obviousness rejection

Claims 1, 7, 8, 10 to 12, 16 to 21, 24, 25, 27, 28 and 30 to 35 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Pat. No. 4,882,318 in view of Vlodavsky et al., Adv. Exp. Med. Biol., 13:317-27 (1992). Applicants respectfully traverse the rejection.

As stated in the Action, Vlodavsky teaches that, to treat cancer, oligosaccharide compounds derived from heparin should have a high inhibition of heparanase activity. See, for example, Office Action at page 5; and Vlodavsky at the bottom of page 317. The Action further notes that Vlodavsky teaches that, to treat cancer, an oligosaccharide should minimize the release of bFGF, which is undesirable. See, for example, Office Action at page 6.

However, the Action goes on to state that, “although Vlodavsky teaches the inhibition of tumor metastasis would best be achieved by oligosaccharides with 16 or more sugar units, Vlodavsky does not [teach that] oligosaccharides with less than 10 units would be ineffective in treating tumor metastasis.” Office Action at page 6.

In response, Applicants respectfully point out that Vlodavsky clearly states that “heparin derived oligosaccharides containing 8-10 sugar units exhibited a high bFGF releasing activity, but failed to inhibit the heparanase enzyme.” Vlodavsky, page 323, second full paragraph (emphasis added). By contrast, heparin species containing 16 or more units efficiently inhibited both heparanase and tumor metastasis. Vlodavsky at page 317.

Thus, Vlodavsky teaches away from the claimed invention. Specifically, Vlodavsky teaches that:


- a) inhibition of heparanase results in inhibition of tumor metastasis;
- b) release of bFGF promotes tumor metastasis;
- c) oligosaccharides of 8 to 10 units exhibited high bFGF releasing activity; and
- d) oligosaccharides of 8 to 10 units failed to inhibit heparanase;

In view of these teachings, the skilled artisan would not have been motivated to make or use oligosaccharides of 10 or less units to treat cancer.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

III. CONCLUSION

All of the issues raised in the Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore Applicants respectfully request a Notice of Allowance to this effect.

Respectfully submitted,

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Encls.

Request for Continued Examination, with fee
Petition for three-month extension, with fee